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Attorney Docket No. 5470.378

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re: Kole

Confirmation No. 3535

Application No.: 10/672,501

Group Art Unit: 1645

Filed: September 26, 2003

For: *Methods and Compositions for Modifications of Splicing of pre-mRNA*

Date: May 5, 2004

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)**

Sir:

Attached is a list of documents on Form PTO-1449, together with a copy of any listed foreign patent document and/or non-patent literature. A copy of any listed U.S. patent and/or U.S. patent application publication is not provided herewith in accordance with the waiver by the U.S. Patent and Trademark Office of requirements under 37 C.F.R. § 1.98(a)(2)(i) for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC § 371 after June 30, 2003.

It is requested that these documents be considered by the Examiner and officially made of record in accordance with the provisions of 37 C.F.R. § 1.56 and Section 609 of the MPEP.

No fee is believed due. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,

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*Cathy A. Schetzina*  
Cathy A. Schetzina

<b>FORM PTO-1449</b> U.S. Department of Commerce Patent and Trademark Office				Attorney Docket Number 5470.378		Serial No. 10/672,501	
LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)							
Applicants: Kole							
Filing Date: September 26, 2003						Group 1645	
<b>U. S. PATENT DOCUMENTS</b>							
Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate	
	1.	5,023,243	06/11/91	Tullis			
	2.	5,149,797	09/22/92	Pederson et al.			
	3.	5,220,007	06/15/93	Pederson et al.			
<b>FOREIGN PATENT DOCUMENTS</b>							
		Document Number	Date	Country	Class	Subclass	Translation Yes   No
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
	4.	"Antisense Used to Correct Genetic Defect" <i>Nature Biotechnology</i> 14:1637 (1996)					
	5.	Baudys et al. "Stabilization and Intestinal Absorption of Human Calcitonin" <i>Journal of Controlled Release</i> 39:145-151 (1996)					
	6.	Bennett "Antisense Research" <i>Science</i> 271:434 (1996)					
	7.	Bennett et al. "Cationic Lipids Enhance Cellular Uptake and Activity of Phosphorothioate Antisense Oligonucleotides" <i>Molecular Pharmacology</i> 41(6):1023-1033 (1992)					
	7.	DeLong et al. "Novel Cationic Amphiphiles as Delivery Agents for Antisense Oligonucleotides" <i>Nucleic Acids Research</i> 27(16):3334-3341 (1999)					
	9.	Dobkin and Bank "Reversibility of IVS 2 Missplicing in a Mutant Human $\beta$ -Globin Gene" <i>The Journal of Biological Chemistry</i> 260(30):16332-16337 (1985)					
	10.	Dominski and Kole "Cooperation of Pre-mRNA Sequence Elements in Splice Site Selection" <i>Molecular and Cellular Biology</i> 12(5):2108-2114 (1992)					
	11.	Dominski and Kole "Identification and Characterization by Antisense Oligonucleotides of Exon and Intron Sequences Required for Splicing" <i>Molecular and Cellular Biology</i> 14(11): 7445-7454 (1994)					
	12.	Dominski and Kole "Identification of Exon Sequences Involved in Splice Site Selection" <i>Journal of Biological Chemistry</i> 269(38):23590-23596 (1994)					
	13.	Dominski and Kole "Restoration of Correct Splicing in Thalassaemic Pre-mRNA by Antisense Oligonucleotides" <i>Proc. Natl. Acad. Sci.</i> 90:8673-8677 (1993)					
	14.	Dominski and Kole "Selection of Splice Sites in Pre-mRNAs with Short Internal Exons" <i>Molecular and Cellular Biology</i> 11(12):6075-6083 (1991)					
	15.	Friedman et al. "Correction of Aberrant Splicing of the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Gene by Antisense Oligonucleotides" <i>Journal of Biological Chemistry</i> 274(51):36193-36199 (1999)					

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DATE CONSIDERED

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Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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## LIST OF DOCUMENTS CITED BY APPLICANT

(Use several sheets if necessary)

Applicants: Kole

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Group  
1645

- |     |  |
|-----|--|
| 16. | Furdon and Kole "Inhibition of in Vitro pre-mRNA Splicing by Antisense Deoxyribonucleotide Analogues" <i>Journal of Cellular Biochemistry Suppl.</i> 130:#K210 (1989) (Abstract)   |
| 17. | Furdon and Kole "The Length of the Downstream Exon and the Substitution of Specific Sequences Affect Pre-mRNA Splicing In Vitro" <i>Molecular and Cellular Biology</i> 8(2): 860-866 (1988)  |
| 18. | Furdon et al. "RNase H Cleavage of RNA Hybridized to Oligonucleotides Containing Methylphosphonate, Phosphorothioate and Phosphodiester Bonds" <i>Nucleic Acids Research</i> 17(22):9192-9204 (1989)   |
| 19. | Gorman et al. "Restoration of Correct Splicing of Thalassemic B-Globin Pre-mRNA by Modified U1 snRNAs" <i>Journal of Biological Chemistry</i> 275(46):35914-35919 (2000)   |
| 20. | Gorman et al. "Stable Alteration of Pre-mRNA Splicing Patterns by Modified U7 Small Nuclear RNAs" <i>Proc. Natl. Acad. Sci. USA</i> 95:4929-4934 (1998)  |
| 21. | Gura "Antisense Has Growing Pains" <i>Science</i> 270:575-577 (1995)   |
| 22. | Kole and Weissman "Accurate In Vitro Splicing of Human $\beta$ -Globin RNA" <i>Nucleic Acids Research</i> 10(18):5429-5445 (1982)  |
| 23. | Kole et al. "Pre-mRNA Splicing as a Target for Antisense Oligonucleotides" <i>Advanced Drug Delivery Reviews</i> 6:271-286 (1991)  |
| 24. | Kulka et al. "Site Specificity of the Inhibitory Effects of Oligo (nucleoside Methylphosphonate)s Complementary to the Acceptor Splice Junction of Herpes Simplex Virus Type 1 Immediate Early mRNA 4" <i>Proc. Natl. Acad. Sci. USA</i> 86:6868-6872 (1989) |
| 25. | Lacerra et al. "Restoration of Hemoglobin A Synthesis in Erythroid Cells from Peripheral Blood of Thalassemic Patients" <i>PNAS</i> 97(17):9591-9596 (2000)  |
| 26. | Lewis et al. "A Common Human $\beta$ Globin Splicing Mutation Modeled in Mice" <i>Blood</i> 91(6):2152-2156 (1998)   |
| 27. | Mercatante et al. "Modification of Alternative Splicing of Bcl-x Pre-mRNA in Prostate and Breast Cancer Cells" <i>Journal of Biological Chemistry</i> 276(19):16411-16417 (2001)   |
| 28. | Miller et al. "Gene Transfer and Antisense Nucleic Acid Techniques" <i>Parasitology Today</i> 10(3):92-97 (1994)   |
| 29. | Milligan et al. "Current Concepts in Antisense Drug Design" <i>J. Medicinal Chemistry</i> 36(14):1923-1937 (1993)  |
| 30. | Munroe "Antisense RNA Inhibits Splicing of Pre-mRNA In Vitro" <i>The EMBO Journal</i> 7(8):2523-2532 (1988)  |
| 31. | Rapaport et al. "Antimalarial Activities of Oligodeoxynucleotide Phosphorothioates in Chloroquine-Resistant <i>Plasmodium falciparum</i> " <i>Proc. Natl. Acad. Sci. USA</i> 89:8577-8580 (1992)   |
| 32. | Reed and Maniatis "Intron Sequences Involved in Lariat Formation during Pre-mRNA Splicing" <i>Cell</i> 41:95-101 (1985)  |
| 33. | Rojanasakul "Antisense Oligonucleotide Therapeutics: Drug Delivery and Targeting" <i>Advanced Drug Delivery Reviews</i> 18:115-131 (1996)  |
| 34. | Ruskin and Green "Specific and Stable Intron-Factor Interactions are Established Early During in Vitro Pre-mRNA Splicing" <i>Cell</i> 43:131-142 (1985)  |
| 35. | Ryder et al. "Sequence-Specific Affinity Selection of Mammalian Splicing Complexes" <i>Nuc. Acids. Res.</i> 18(24):7373-7374 (1990)  |
| 36. | Sazani and Kole "Therapeutic Potential of Antisense Oligonucleotides as Modulators of Alternative Splicing" <i>Journal of Clinical Investigation</i> 112(4):481-486 (2003)   |

EXAMINER  
\*EXAMINER

DATE CONSIDERED

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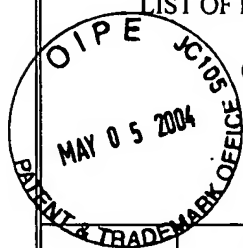
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Group  
1645

- |     |   |
|-----|---|
| 37. | Schmajuk et al. "Antisense Oligonucleotides with Different Backbones" <i>Journal of Biological Chemistry</i> 274(31):21783-21789 (1999)   |
| 38. | Sierakowska et al. "Antibodies to hnRNP Core Proteins Inhibit <i>In Vitro</i> Splicing of Human $\beta$ -Globin Pre-mRNA" <i>Nucleic Acids Research</i> 14(3):5241-5254 (1986)  |
| 39. | Sierakowska et al. "Inhibition of Pre-mRNA Splicing by 5-Fluoro-, 5-Chloro-, and 5-Bromouridine" <i>Journal of Biological Chemistry</i> 264(32):19185-19191 (1989)  |
| 40. | Sierakowska et al. "Repair of Thalassemic Human B-Globin mRNA in Mammalian Cells by Antisense Oligonucleotides" <i>Proc. Natl. Acad. Sci. USA</i> 93:12840-12844 (1996)   |
| 41. | Stein "Does Antisense Exist?" <i>Nature Medicine</i> 1:1119-1121 (1995)   |
| 42. | Stein and Cheng "Antisense Oligonucleotides as Therapeutic Agents – Is the Bullet Really Magical?" <i>Science</i> 261:1001-1012 (1993)  |
| 43. | Stull et al. "Antigene Ribozyme and Aptamer Nucleic Acid Drugs: Progress and Prospects" <i>Pharmaceutical Research</i> 12(4):465-483 (1995)   |
| 44. | Suter et al. "Double-Target Antisense U7 snRNAs Promote Efficient Skipping of an Aberrant Exon in Three Human $\beta$ -Thalassemic Mutations" <i>Human Molecular Genetics</i> 8(13):2415-2423 (1999)                      |
| 45. | Tian et al. "Selection of Novel Exon Recognition Elements from a Pool of Random Sequences" <i>Molecular and Cellular Biology</i> 15(11):6291-6298 (1995)  |
| 46. | Tseng et al. "Antisense Oligonucleotide Technology in the Development of Cancer Therapeutics" <i>Cancer Gene Ther.</i> 1:65-71 (1994)   |
| 47. | Uhlmann et al. "Antisense Oligonucleotides: A New Therapeutic Principle" <i>Chem. Rev.</i> 90:544-579 (1990)  |
| 48. | Volloch et al. "Inhibition of Pre-mRNA Splicing by Antisense RRNA in Vitro: Effect of RNA Containing Sequences Complementary to Exons" <i>Biochemical and Biophysical Research Communications</i> 179(3):1593-1599 (1991) |
| 49. | Wagner "Gene Inhibition Using Antisense Oligodeoxynucleotides" <i>Nature</i> 372:333-335 (1994)   |
| 50. | Wagner "The State of the Art in Antisense Research" <i>Nature Medicine</i> 1:1116-1118 (1995)   |
| 51. | Weiss "Upping the Antisense Ante" <i>Science News</i> 139:108-109 (1991)  |
| 52. | Westerman et al. "Inhibition of Expression of SV40 Virus Large T-Antigen by Antisense Oligodeoxyribonucleotides" <i>Biomed. Biochim. Acta.</i> 48:85-93 (1989)  |
| 53. | Wu-Pong "Oligonucleotides: Opportunities for Drug Therapy Research" <i>Pharmaceutical Technology</i> 18:102-114 (1994)  |
| 54. | Zhuang and Weiner "A Compensatory Base Change in Human U2 snRNA Can Suppress a Branch Site Mutation" <i>Genes &amp; Development</i> 3(10):1545-1552 (1989)  |

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